

37. (New) The method of claim 26, wherein the second element is formed of a material that buckles to allow a bend to occur in the second element after attaching the second element to the first element in a body lumen that is curved or angled.

REMARKS

Applicant has amended the specification to correct references to superior and inferior ends. Further, Applicant has amended claims 26 - 27, canceled claims 28 and 29, and added new claims 30 - 37. Claims 26, 27, and 30 - 37 are now pending in the present application.

Reexamination and reconsideration of the application, as amended, are respectfully requested.

The Examiner has rejected claim 26 under 35 U.S.C. §112, second paragraph, for insufficient antecedent basis for the limitation "the graft." In response, Applicant has amended claim 26, changing "the graft" in lines 6 and 7 to "the first element."

The Examiner also has rejected claims 26-27 under 35 U.S.C. §102(b) and (e) as being anticipated by Lazarus (U.S. Patent No. 5,693,088). Additionally, the Examiner rejected claims 26-27 under 35 U.S.C. §102(e) as being anticipated by Leonhardt et al. (U.S. Patent No. 5,713,917). Further, the Examiner has rejected claims 26-29 under 35 U.S.C. §103(a) as being unpatentable over Pierce (U.S. Patent No. 6,152,956) in view of Lazarus. Applicant has amended claim 26 to now include limitations previously recited in canceled claims 28 and 29 as well as a second element of a graft assembly that is attached to the first element subsequent to activating attachment devices. It is respectfully submitted that none of the cited references including Lazarus, Leonhardt and Pierce, either alone or in combination, teach configuring a

bifurcation junction of a first element at a point of bifurcation and a second element that is attached to a first element subsequent to actuating attaching devices. In particular, it is believed that there is no teaching in either Pierce or Lazarus which motivates the combination of the subject matter disclosed therein. As such, it is respectfully submitted that the combination of the teachings of Pierce and Lazarus can only be made through improper hindsight. Moreover, it is clear that the combination of these references lack, *inter alia*, the teaching of attaching a second element subsequent to affixing the recited first and second legs. Therefore, Applicant believes that claim 26 as amended defines subject matter that is patentable over the cited art. Moreover, Applicant believes that claims 27 and 30 - 37 are also patentable because they depend from independent claim 26. Accordingly, it is respectfully requested that the claims be allowed.

CONCLUSION

Applicants have attempted to respond to each rejection set forth in the outstanding Office action. In view of the above amendments and remarks, it is respectfully requested that this

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application be passed to issue. Attached hereto is a marked-up version of the changes made. The attached page is captioned "**Version With Markings To Show Changes Made**".

Respectfully submitted,

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Version With Markings to Show Changes MadeIN THE SPECIFICATION

Please amend the specification as follows:

At page 7, replace the paragraph beginning at line 17 and ending at page 8, line 7, with the following language:

In accordance with one embodiment of the modular graft of the present invention, exemplified in FIG. 2, a first element 20 and a second element 60 of a modular bifurcated graft are assembled before insertion into the patient's vascular system. The first element 20 includes a tubular docking section 22 having a continuous wall 24 between a superior end 26 and an inferior end 28 defining a lumen and is adapted to be expanded from a collapsed condition to an expanded condition. Protruding from the [superior] inferior end of the docking section are a left limb 30 and a right limb 32, each having a continuous wall 34, 36 between [inferior] superior ends 38, 40 and [superior] inferior ends 42, 44 respectively, defining lumens and being adapted to be expanded from a collapsed condition to an expanded condition. At a point of connection between the left limb 30 and right limb 40 is a graft bifurcation junction 45. The wall 24 of the docking section 22 is continuously connected with the walls 34, 36 of the left limb and the right limb, to define a bifurcated lumen of the first element 20. The docking section 22 and limbs 34, 36 of the first element 20 may be manufactured from any flexible surgical implantable material such as DacronTM which is known to be sufficiently biologically inert, non-biodegradable, and

durable. One material found to be satisfactory is DeBakey soft woven Dacron™ vascular prosthesis (uncrimped) sold by USCI.

At page 8, replace the paragraph beginning at line 26 and ending on page 9, line 7, with the following paragraph:

The second element 60 includes a tubular segment 61 having a continuous wall 62 between a superior end 64 and an inferior end 66 defining a lumen adapted to be expandable from a collapsed condition to an expanded condition, and may be made from the same flexible biocompatible material as the docking section 22 and limbs 30, 32 of the first element 20. A fourth support structure 68 may be connected to the [inferior] superior end 64 and a fifth support structure 70 may be connected to the [superior] inferior end 66 of the tubular segment 61. In alternative embodiments, additional support structures may be added, as required, in the space between the fourth 68 and fifth 70 support structures, as may be required. For example, a sixth support structure 71 is shown attached to the inner lumen of the tubular segment 61 adjacent to its [inferior] superior end 64.

At page 12, replace the paragraph beginning at line 1 and ending on page 13, line 2, with the following paragraph:

After deployment of the first element 20, the second element 60 is loaded into a delivery capsule (not shown) in compressed condition, and is passed over the first guide-wire 51 until it extends into the aorta 12, whereupon it is released from the delivery capsule to assume its

expanded condition. As exemplified in FIG. 6, the second element 60 in its expanded condition is positioned so that the wall 62 of the tubular segment 61 is compressed at its superior end 64 into contact with the aortic wall 12. The fourth support system 68 anchors the tubular segment 61 against migration, and may contribute to a seal being formed between the tubular segment 61 and the aortic wall 12. Preferably, a sixth support structure 71 may be attached to the lumen of the tubular section at its superior end 64 to enhance the seal. In another embodiment of the second element 20, previously described and exemplified in FIG. 7, the fourth support structure 68 is positioned substantially within the lumen of the tubular segment 61, allowing the fourth support structure 68 to play a more significant role in forming a seal between the tubular segment 61 and the aortic wall 12. If hooks 52 are attached to the fourth support structure 68, they may be configured to protrude over the superior end 64 of the tubular segment 61 to engage with the aorta 12, or they may be adapted to protrude through the wall of the tubular segment 61. In either embodiment, the inferior end 66 of the tubular segment 61 is compressed into contact with the inner wall 24 of the docking section 22 by the fifth support structure (not shown in FIG. 6 but exemplified in FIG. 2 and in section in FIG. 10). The diameter of the tubular segment 61 may vary from its superior end [66] 64 to its inferior end [64] 66, but in the expanded condition the diameter of the superior end [66] 64 must be slightly larger than the aortic neck 12 to which it is to be attached, and the diameter of the inferior end [64] 66 must be slightly larger than the diameter of the lumen of the docking section 22 to which it is to be attached. It will be appreciated that in the event that the material of the first 20 and second 60 elements is not

elastically expandible, and that if the diameter of an element is smaller than the diameter of the lumen to which it is to be attached, a proper fluid seal cannot be formed.

IN THE CLAIMS

Please amend claims 26 and 27, as follows:

26. (Amended) A method for repairing [a body lumen] an aorta in an area proximate renal arteries and having a point of bifurcation, using a graft assembly including a first element and a second element, the first element having a bifurcation junction, first and second legs extending from the bifurcation junction, a sealing stent disposed superior to the bifurcation junction, and a plurality of attaching devices at least one of which is operatively associated with each of the first and second legs, comprising:

inserting the [graft] first element within the [body lumen] aorta;

configuring the bifurcation junction of the [graft] first element at the point of bifurcation of the [body lumen] aorta such that the graft spans and is supported by the point of bifurcation; [and]

10 actuating the attaching devices to affix the first and second legs within the [body lumen.] aorta;

attaching the second element to the first element subsequent to actuating the attaching devices to affix the first and second legs; and

15 fixating the second element superior to the renal arteries.

27. (Amended) The method of claim 26, wherein the first element includes a docking site [and the graft assembly further includes a docking site and the graft assembly further includes a second element], further comprising:

attaching the second element to the docking site of the first element.